C&G Containers Scientific

"The Total Package!"

USP 788 LOW PARTICLE CONTAINERS

Essential solutions for pharmaceutical, biotech, and medical industries where critical or controlled environments are utilized.

LOW PARTICLE GLASS CONTAINERS

Processed and validated to meet or exceed USP <788> particulate limits.

ADVANCED CLOSURE SYSTEMS

Polypropylene closures with chemically inert PTFE-faced liners, free of adhesives.

MATERIAL OPTIONS

Clear and amber glass containers in a wide range of sizes for diverse needs and applications.

CERTIFICATIONS

Certificate of Process, Certificate of Analysis, and Quality Assurance available for traceability.

(800) 396-7123
www.cgcontainers.com

Critical Environment Needs

Contact us today to learn more about our specialized glass containers, custom options, and certifications.

WHAT IS USP 788

The United States Pharmacopoeia, USP <788> is a standard for determining the count and size of undissolved particles in injection solutions. It applies to particles ≥ 10 and ≥ 25 µm in size.

Types of Injections:

- Large Volume Parenteral/Injection (LVP/LVJ): > 100 mL
- Small Volume Parenteral/Injection (SVP/SVJ): < 100 mL

USP <788> provides two methods for detecting particulates in large volume parenteral (LVP) and small volume parenteral (SVP):

- Method 1 – Light Obscuration: commonly used method
- Method 2 – Microscopic Particle Count: used if Method 1 exceeds limits.

USP 788 LIMITS

USP <788> places limits on the amount of subvisible particles allowed in injections.

These limits are harmonized with the European Pharmacopoeia (EP) and Japanese Pharmacopoeia (JP).

The USP <788> limits are specific to the types of injections and the methods used for detection.

	Method 1 (e.g., Beckman® HAIC)		**Method 2 (e.g., Halo Labs Aura®)**	
Particle equivalent diameter	≥ 10 µm	≥ 25 µm	≥ 10 µm	≥ 25 µm
Container > 100 mL	≤ 25 per mL	≤ 3 per mL	≤ 12 per mL	≤ 2 per mL
Container ≤ 100 mL	≤ 6,000 per container	≤ 600 per container	≤ 3,000 per container	≤ 300 per container

WHY USP 788 MATTERS

Particulate matter, often too small to see with naked eye, can pose risks to patient safety and product shelf life.

Ensuring injectable drugs meet USP <788> requirements is crucial to minimize these risks.

USP 788 COMPLIANCE

- Various container types and sizes compliant with USP <788>.
- Common applications include pharmaceutical, biotech, and medical industries.
- Typical certifications include Certificate of Process, Certificate of Analysis, and Quality Assurance.